

**State of California
Department of Public Health**

RADIOLOGIC HEALTH BRANCH

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Related Document: X-ray Inspection Manual

Policy Title: CINERADIOGRAPHY

1.0 PURPOSE:

The purpose of this document is to assist the staff of the Department of Public Health's Radiologic Health Branch in evaluating compliance with the requirements found in the fluoroscopy statutes and regulations as they pertain to cineradiography and related fluoroscopic modalities. It is important to note that while this policy statement is not a regulation, and compliance with it is not required, compliance with the applicable statutes and regulations cited in this document is mandatory.

2.0 AUTHORITY AND REFERENCE

The regulations (CCR, title 17, § 30400) define fluoroscopy as "a radiological examination utilizing fluorescence for the observation of the transient image."

The regulations (CCR, title 17, § 30307(a)(1) through (b)(3)) describe standards and procedures for the inspection of fluoroscopy equipment.

The regulations (CCR, title 17, § 30307(b)(4)) further provide that "On cineradiography equipment, the exposure rates to which patients are normally subjected shall be determined at least once each year, and immediately following alterations or replacement of a major component, such as the X-ray tube, the exposure controls, the imaging assembly, and the power source."

The regulations (CCR, title 17, § 30305), specify requirements for the use of X-ray in the healing arts. The requirements apply to use of X-rays in medicine, dentistry, osteopathy, chiropractic, podiatry, and veterinary medicine. This section requires, by reference, sufficient maintenance to keep equipment in compliance with all applicable radiation protection sections of the Code of Federal Regulations, Title 21, Chapter 1, Subchapter J, Part 1020, Sections 1020.30, 1020.31 (Radiographic Equipment), and Section 1020.32 (Fluoroscopic Equipment).

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3.0 PROCEDURES

Cineradiography (“cine”) is the high-speed sequential acquisition of images by a radiographic or fluoroscopic machine. Cine was developed to improve the visualization of small vessels filled with contrast media by “freezing” motion, and employed framing rates of 15, 30, 45 and 60 frames per second (fps). In its original configuration, cine movie film captured the rapid serial images produced on an image intensifier. Radiographic tube currents approaching 1,000 milliamps were required to generate the brightness necessary to adequately expose the cine film. Today, digital acquisition technology permits the use of fluoroscopic tube currents as low as 20 milliamps. In the April 1, 2006 version of 21 CFR 1020.30, the definition of cineradiography was updated to accommodate changes in technology. *Mode of operation* now defines cine as an imaging modality that records images on film (analog) as well as through electronic media (digital).

The development of pulse-rate technology has reduced fluoroscopic patient exposure during the viewing of the transient image. This capability is typically expressed as pulses-per-second (pps); pulse rates of 2, 8, 16, or 32 pps are typical. Operation of the fluoroscope in a pulse-rate mode while viewing the transient image is not considered cineradiography.

Also excluded from this definition is the utilization of older analog systems that employ cut-film magazines, long-leg changers, or the sequential acquisition of spot-film images for swallow procedures.

4.0 PRACTICAL EXAMPLES

The following examples, given in a scenario, question and answer format, provide typical situations that arise in practice. The examples do not address every possible situation but provide guidance for complying with the regulations pursuant to sections 30307 and 30305.

Example 1

Scenario: A mobile C-arm has the following capabilities: fluoroscopy, high-level fluoroscopic output, fluoroscopy in a pulse-rate mode to reduce patient dose, and radiography.

Question: Regarding machine outputs, what measurements must be included in the annual physics evaluation to satisfy regulatory requirements?

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Answer: The Department evaluates compliance with the regulations concerning the routine patient exposure rate and the maximum possible output rate. If a machine has high-level control output capability, that exposure rate must also be included. Technical factors must be provided for all applicable output rates. A related test required by regulation of all fluoroscopes, and of an ongoing nature, is the “weekly fluoroscopic monitoring” test, required by section 30307(b)(2). Implementation of this weekly testing is normally accomplished through consultation with your physics support vendor, though the testing itself is usually performed by radiology staff.

Example 2

Scenario: We are a pain-management practice and only use our mobile C-arm for clinical studies related to this specialty. Our C-arm has a modality that acquires digital images at 15, 30, and 45 frames per second. We are told that this feature cannot be easily disabled.

Question: Does the digital acquisition modality qualify as cine, and must measurements be made and reported in the annual physics report?

Answer: Although the regulations require that exposure rates be known for cineradiography, the Department will accept a written statement in the registrant’s Radiation Protection Program affirming that this modality has no clinical application and will not be used. However, this is subject to verification by the Department at the time of inspection.

Example 3

Scenario: Our facility performs about a dozen esophograms each week. We have converted from the older 105 mm spot-film format to digital.

Question: Are these studies considered cine, thus requiring special measurements by our physicist?

Answer: No.

Example 4

Scenario: We perform cerebral angiography and only use frame rates of 2 or 4 frames-per-second. Our machine will also acquire images at framing rates of 15, 30, 45 and 60 frames per second, although we never use it at those higher rates.

Question: Does this constitute cine, and must measurements be made and reported in the annual physics evaluation?

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Answer: Yes. The higher framing rates, i.e., 15, 30, etc., qualify as cine and must be evaluated even though they are not used clinically. Although the ideal would be disablement of these higher rates, this may not be easily achieved. An acceptable alternative is to obtain minimal data in one of the framing rates. NOTE: Angiographic exposure rates can be substantial. Although operation in these lesser framing rates is not considered cine, we strongly recommend that patient exposure rates under these clinical conditions be determined.

Example 5

Scenario: Our equipment is dedicated to perform run-offs and also employs an old long-leg changer. It cannot operate at a framing rate faster than 4 frames-per-second.

Question: Does this constitute cine? Must any special measurements be made?

Answer: No.

NOTE: Additional requirements regarding fluoroscopy are found in California Code of Regulations, title 17, as follows:

Section 30255: Specifies requirements for notices, instructions, and reports to personnel and applies to all persons who receive, possess, use, own, or transfer equipment registered with the Department.

Section 30305: Specifies requirements for the use of X-ray in the healing arts. The requirements apply to use of X-rays in medicine, dentistry, osteopathy, chiropractic, podiatry, and veterinary medicine.

Section 30307: Specifies requirements for fluoroscopic equipment and operating procedures while using fluoroscopic equipment.

Section 30253: This section incorporates, by reference, section 20.1101 of title 10, Code of Federal Regulations (January 1, 2005), which requires a user to develop, document, and implement a radiation protection program commensurate with the scope of activities and sufficient to ensure compliance. It further requires the user to review, at least annually, the program's content and implementation.



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Date